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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/749,962 Confirmation No. 2164
Applicants : Chandrika Govardhan et al.
Filed : December 31, 2003
TC/A.U. : 1641
Examiner : Christine J. Saoud

Docket No. : Altus-4
Customer No. : 1473
For : HUMAN GROWTH HORMONE CRYSTALS AND
METHODS FOR PREPARING THEM

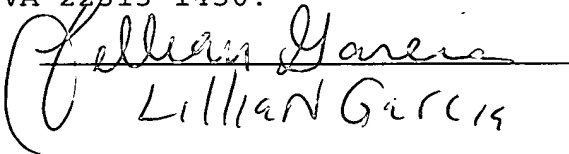
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Date of Deposit: January 11, 2005

I hereby certify that this certification and the following papers and fees:

1. Transmittal Letter (in duplicate);
2. Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97(b);
3. Form PTO/SB/08A (in duplicate);
4. 33 cited documents; and
5. Postcard Receipt

are being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to Mail Stop Amendment, Hon. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


Lillian Garcia



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Commissioner for Patents New York, New York 10020
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR
INFORMATION DISCLOSURE STATEMENT

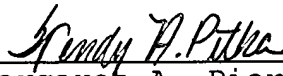
Sir:

Transmitted herewith is an Information Disclosure Statement in the above-identified application. This Statement is being submitted more than three months from the application filing date but before the mailing of a first Office Action on the merits under 37 C.F.R. § 1.97(b)(3), or a Notice of Allowance under 37 C.F.R. § 1.311, therefore it is timely without the payment of any additional fees.

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EV 371748245 US

The Director is hereby authorized to charge payment of any additional fees required in connection with the accompanying Information Disclosure Statement, or credit any overpayment, to Deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.

Respectfully submitted,



Margaret A. Pierri (Reg. No. 30,709)

Attorney for Applicants

Wendy A. Petka (Reg. No. 53,459)

Agent for Applicants

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Commissioner for Patents New York, New York 10020
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.56 AND § 1.97(b)

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicants,
through their attorneys, make of record the following documents,
copies of which are enclosed herewith*:

United States Patents and Patent Applications

4,342,832, Goeddel et al., issued August 3, 1982
4,816,568, Hamilton, Jr. et al., issued March 28, 1989
4,917,685, Viswanathan et al., issued April 17, 1990
5,633,352, Dalbøge et al., issued May 27, 1997

* A completed Form PTO/SB/08A listing these documents is
attached hereto.

Express Mail No.
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5,654,010, Johnson et al., issued August 5, 1997
 5,667,808, Johnson et al., issued September 16, 1997
 5,691,169, Dalbøge et al., issued November 25, 1997
 5,705,482, Christensen et al., issued January 6, 1998
 5,734,026, Florin-Robertsson et al., issued March 31, 1998
 5,780,599, Junker et al., issued July 14, 1998
 5,788,959, Singh, issued August 4, 1998
 5,849,700, Sørensen et al., issued December 15, 1998
 5,849,704, Sørensen et al., issued December 15, 1998
 5,981,485, O'Connor et al., issued November 9, 1999
 6,022,858, Sorensen et al., issued February 8, 2000
 6,066,470, Nishimura et al., May 23, 2000
 6,117,984, Junker et al., issued September 12, 2000
 6,267,981 B1, Okamoto et al., issued July 31, 2001
 6,309,859 B1, Nishimura et al., issued October 30, 2001
 6,359,118 B1, Margolin et al., issued March 19, 2002
 6,376,461 B1, Igari et al., issued April 12, 2002
 6,448,225 B2, O'Connor et al., issued September 10, 2002
 6,541,606 B2, Margolin et al., issued April 1, 2003
 2002/0009491 A1, Rothbard et al., issued January 24, 2002
 2002/0142050 A1, Straub et al., issued October 3, 2002
 2003/0013653 A1, O'Connor et al., issued January 16, 2003
 2003/0099663 A1, Fleitmann et al., issued May 29, 2003
 2004/0029777 A1, Ando et al., issued April 9, 2003

PCT Patent Applications

WO 92/00998, Junker et al., published January 23, 1992
 WO 94/03198, O'Connor et al., published February 17, 1994
 WO 95/28174, Clark et al., published October 26, 1995
 WO 96/07397 A2, Cherif-Cheikh et al., published March 14, 1996
 WO 96/07399 A1, Igari et al., published March 14, 1996
 WO 96/21459, Christensen et al., published July 18, 1996
 WO 96/21460, Christensen et al., published July 18, 1996
 WO 97/01331, Okamoto et al., published January 16, 1997
 WO 99/55310, Margolin et al., published November 4, 1999
 WO 01/24822 A2, Fleitmann et al., published April 12, 2001

Australian Patent

AU 686,567, O'Connor et al, issued February 12, 1998

Canadian Patent

CA 2,086,087, Junker et al., issued September 14, 1999
 CA 2,147,482, Florin-Robertsson et al., issued
 September 23, 2003

European Patents and Application

EP 0 303 746 A1, Hamilton Jr. et al., published
February 22, 1989
EP 0 540 582 B1, Junker et al., issued August 31, 1994
EP 0 652 766 B1, O'Connor et al., issued November 8, 2000
EP 0 779 806 B1, Igari et al., issued November 8, 2000

Other Documents

BENNANI-BAITI et al., "Physical Linkage of the Human Growth Hormone Gene Cluster and the Skeletal Muscle Sodium Channel α -Subunit Gene (SCN4A) on Chromosome 17," *Genomics*, 29, 647-652, 1995.

CHANTALAT et al., "The Crystal Structure of Wild-Type Growth Hormone at 2.5 Å Resolution," *Protein and Peptide Letters*, Vol. 2, 333-340, 1995.

CLARK et al., "Long-acting Growth Hormones Produced by Conjugation with Polyethylene Glycol," *The Journal of Biological Chemistry*, Vol. 271, No. 36, 21969-21977, 1996.

CLARKSON et al., "Crystallization and X-ray Data Collection on Human Growth Hormone," *Journal of Molecular Biology*, Vol. 208, 719-721, 1989.

GENENTECH, "Product Information - Nutropin Depot Full Prescribing Information," <http://www.gene.com/gene/products/information/opportunistic/nutropin-depot/insert.jsp>.

HARO et al., "Divalent Metal Cation Chelators Enhance Chromatographic Separation of Structurally Similar Macromolecules: Separation of Human Growth Hormone Isoforms," *Journal of Chromatography B*, Vol. 720, 39-47, 1998.

HERBERGER et al., "Characterization of Prolease® Human Growth Hormone PLGA Microspheres Produced Using Different Solvents," *Proc. Intl. Symp. Controlled Release of Bioactive Materials*, Vol. 23, 835-836, 1996.

HUMAN GENOME SCIENCES, "Albutropin," <http://www.hgsi.com/products/albutropin.html>.

JONES et al., "Crystallization of Authentic Recombinant Human Growth Hormone," *Biotechnology*, Vol. 5, 499-500, 1987.

KATAKAM et al., "Controlled Release of Human Growth Hormone in Rats Following Parenteral Administration of Poloxamer Gels," *Journal of Controlled Release*, Vol. 49(1), 21-26, 1997.

KIM et al., "Microencapsulation of Dissociable Human Growth Hormone Aggregates within Poly(D,L-lactic-co-glycolic acid)," *International Journal of Pharmaceutics*, Vol. 229(1-2), 107-116, 2201.

LEWIS et al., "Crystalline Human Growth Hormone," *The Journal of the American Chemical Society*, Vol. 80, 4429-4430, 1958.

MCPHERSON et al., "The Growth and Preliminary Investigation of Protein and Nucleic Acid Crystals for X-Ray Diffraction Analysis," *Methods of Biochemical Analysis*, Vol. 23, 249-345, 1976.

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WILHELMI et al., "A New Preparation of Crystalline Anterior Pituitary Growth Hormone," *Journal of Biological Chemistry*, 176, 735-745, 1948.

WU et al., "Application of High-Performance Hydrophobic-Interaction Chromatography to the Characterization of Recombinant DNA-Derived Human Growth Hormone," *Journal of Chromatography*, 500, 595-606, 1990.

Applicants have attached a PTO/SB/08A Form listing these documents. Applicants request that these documents: (1) be fully considered by the Examiner during examination of this application and (2) be printed on any patent that may issue from this application. Applicants also request that a copy of Form PTO/SB/08A, as considered and initialed by the Examiner be returned with the next communication.

The Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of the accompanying transmittal letter setting forth that authorization is transmitted herewith.

Respectfully submitted,

Wendy A. Petka

Margaret A. Pierri (Reg. No. 30,709)
Attorney for Applicants

Wendy A. Petka (Reg. No. 53,459)
Agent for Applicants

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Complete if known

Application Number	10/749,962
Confirmation Number	2164
Filing Date	December 31, 2003
First Named Inventor	Chandrika Govardhan
Art Unit	1641
Examiner Name	Christine J. Saoud
Attorney Docket Number	Altus-4

U.S. PATENT DOCUMENTS

Examiner initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US-4,342,832	08-03-1982	Goeddel et al.	
		US-4,816,568	03-28-1989	Hamilton, Jr. et al.	
		US-4,917,685	04-17-1990	Viswanathan et al.	
		US-5,633,352	05-27-1997	Dalbøge et al.	
		US-5,654,010	08-05-1997	Johnson et al.	
		US-5,667,808	09-16-1997	Johnson et al.	
		US-5,691,169	11-25-1997	Dalbøge et al.	
		US-5,705,482	01-06-1998	Christensen et al.	
		US-5,734,026	03-31-1998	Florin-Robertsson et al.	
		US-5,780,599	07-14-1998	Junker et al.	
		US-5,788,959	08-04-1998	Singh	
		US-5,849,700	12-15-1998	Sørensen et al.	
		US-5,849,704	12-15-1998	Sørensen et al.	
		US-5,981,485	11-09-1999	O'Conner et al.	
		US-6,022,858	02-08-2000	Sørensen et al.	
		US-6,066,470	05-23-2000	Nishimura et al.	
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		US-6,309,859 B1	10-30-2001	Nishimura et al.	
		US-6,359,118 B2	03-19-2002	Margolin et al.	
		US-6,376,461 B1	04-12-2002	Igari et al.	
		US-6,448,225 B2	09-10-2002	O'Connor et al.	
		US-6,541,606 B2	04-01-2003	Margolin et al.	
		US-2002/0009491 A1	01-24-2002	Rothbard et al.	
		US-2002/0142050 A1	10-03-2002	Straub et al.	
		US-2003/0013653 A1	01-16-2003	O'Conner et al.	
		US-2003/0099663 A1	05-29-2003	Fleitmann et al.	
		US-2004/0029777 A1	04-09-2003	Ando et al.	

Examiner
SignatureDate
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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbol as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

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Sheet	2	of	3		

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Examiner initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ¹ - Number ² - Kind Code ³				
		AU 686567	02-12-1998	O'Connor et al.		
		CA 2,086,087	09-14-1999	Junker et al.		
		CA 2,147,482	09-23-2003	Florin-Robertsson et al.		
		EP 0 303 746 A1	02-22-1989	Hamilton, Jr. et al.		
		EP 0 540 582 B1	08-31-1994	Junker et al.		
		EP 0 652 766 B1	11-08-2000	O'Connor et al.		
		EP 0 779 806 B1	11-08-2000	Igari et al.		
		WO 92/00998	01-23-1992	Junker et al.		
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		WO 95/28174	10-26-1995	Clark et al.		
		WO 96/07397 A2	03-14-1996	Cherif-Cheikh et al.		
		WO 96/07399 A1	03-14-1996	Igari et al.		
		WO 96/21459	07-18-1996	Christensen et al.		
		WO 96/21460	07-18-1996	Christensen et al.		
		WO 97/01331	01-16-1997	Okamoto et al.		
		WO 99/55310	11-04-1999	Margolin et al.		
		WO 01/24822 A2	04-12-2001	Fleitmann et al.		

Examiner Signature		Date Considered	
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NON PATENT LITERATURE DOCUMENTS			
Examiner initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue numbers (s), publisher, city and/or country where published	T ⁶
		BENNANI-BAITI et al., "Physical Linkage of the Human Growth Hormone Gene Cluster and the Skeletal Muscle Sodium Channel α -Subunit Gene (SCN4A) on Chromosome 17," <i>Genomics</i> , 29, 647-652, 1995.	
		CHANTALAT et al., "The Crystal Structure of Wild-Type Growth Hormone at 2.5 Å Resolution," <i>Protein and Peptide Letters</i> , Vol. 2, 333-340, 1995.	

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	CLARKSON et al., "Crystallization and X-ray Data Collection on Human Growth Hormone," <i>Journal of Molecular Biology</i> , Vol. 208, 719-721, 1989.	
	GENENTECH, "Product Information - Nutropin Depot Full Prescribing Information," http://www.gene.com/gene/products/information/opportunistic/nutropin-depot/insert.jsp .	
	HARO et al., "Divalent Metal Cation Chelators Enhance Chromatographic Separation of Structurally Similar Macromolecules: Separation of Human Growth Hormone Isoforms," <i>Journal of Chromatography B</i> , Vol. 720, 39-47, 1998.	
	HERBERGER et al., "Characterization of Prolease® Human Growth Hormone PLGA Microspheres Produced Using Different Solvents," <i>Proc. Intl. Symp. Controlled Release of Bioactive Materials</i> , Vol. 23, 835-836, 1996.	
	HUMAN GENOME SCIENCES, "Albutropin," http://www.hgsi.com/products/albutropin.html .	
	JONES et al., "Crystallization of Authentic Recombinant Human Growth Hormone," <i>Biotechnology</i> , Vol. 5, 499-500, 1987.	
	KATAKAM et al., "Controlled Release of Human Growth Hormone in Rats Following Parenteral Administration of Poloxamer Gels," <i>Journal of Controlled Release</i> , Vol. 49(1), 21-26, 1997.	
	KIM et al., "Microencapsulation of Dissociable Human Growth Hormone Aggregates within Poly(D,L-lactic-co-glycolic acid)," <i>International Journal of Pharmaceutics</i> , Vol. 229(1-2), 107-116, 2201.	
	LEWIS et al., "Crystalline Human Growth Hormone," <i>The Journal of the American Chemical Society</i> , Vol. 80, 4429-4430, 1958.	
	MCPHERSON et al., "The Growth and Preliminary Investigation of Protein and Nucleic Acid Crystals for X-Ray Diffraction Analysis," <i>Methods of Biochemical Analysis</i> , Vol. 23, 249-345, 1976.	
	WEBSTER'S New World Dictionary of Science, Lindley and Moore, Eds., Macmillan, New York, New York, 673, 1998.	
	WILHELMI et al., "A New Preparation of Crystalline Anterior Pituitary Growth Hormone," <i>Journal of Biological Chemistry</i> , 176, 735-745, 1948.	
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